



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1566]

Naming of Drug Products Containing Salt Drug Substances; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Naming of Drug Products Containing Salt Drug Substances" which replaces the draft guidance of the same title that published on December 26, 2013. This guidance describes the United States Pharmacopeia's (USP's) "Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations," which became official on May 1, 2013, and how the Center for Drug Evaluation and Research (CDER) is implementing it.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mamta Gautam-Basak, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-0712.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Naming of Drug Products Containing Salt Drug Substances" that replaces the draft of the same title that published on December 26, 2013 (78 FR 78366). This guidance is being published to explain how CDER is implementing the USP's policy entitled "Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations." It is a naming and labeling policy applicable to drug products that contain an active ingredient that is a salt. The policy stipulates that USP will use the name of the active moiety, instead of the name of the salt, when creating a drug product monograph title and the strength will be expressed in terms of the active moiety. The policy allows for exceptions under specified circumstances. CDER is now applying this policy to new prescription drug products under development under section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355).

The USP Salt Policy became official on May 1, 2013, and USP is now applying it to all new drug product monographs for products that contain an active ingredient that is a salt. It affects the development of new drug products because a USP monograph title for a new drug product, in most instances, serves as the nonproprietary or "established" name of the related drug

product (section 502(e)(3) of the FD&C Act) (21 U.S.C. 352(e)). If a drug product's label or labeling contains a name that is inconsistent with the applicable monograph title, it risks being misbranded (section 502(e)(1)(A)(i) of the FD&C Act).

This guidance describes the USP policy and discusses how CDER and industry can implement the policy. Following the policy will help reduce medication errors caused by a mismatch between the established name and strength on the label of drug products that contain a salt. In addition, we anticipate that this policy will help health care practitioners calculate equivalent doses when changing from one dosage form to another, even if the products contain active ingredients that are different salts, because the strengths and names will both be based on the active moiety.

In the Federal Register of December 26, 2013 (78 FR 78366), this guidance was published as a draft guidance. We have carefully reviewed and considered the comments that were received on the draft guidance and have made changes for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation 21 CFR 10.115. This guidance represents CDER's current thinking on drug product naming nomenclature for new drugs that contain a salt as the active ingredient. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information referenced in this guidance that are related to the burden for the submission of investigational new drug applications are covered under 21 CFR

312 and have been approved under OMB control number 0910-0014. The collections of information referenced in this guidance that are related to the burden for the submission of new drug applications that are covered under 21 CFR 314 have been approved under OMB control number 0910-0001. The submission of prescription drug product labeling under 21 CFR 201.56 and 201.57 is approved under OMB control number 0910-0572.

The guidance also references 21 CFR 201.10 "Drugs; Statement of Ingredients." In the Federal Register of December 18, 2014 (79 FR 75506), FDA published its proposed rule on the electronic distribution of prescribing information for human prescription drugs, including biological products. In Section VII, "Paperwork Reduction Act of 1995," FDA estimated the burden to design, test, and produce the label for a drug product's immediate container and outer container or package, as set forth in 21 CFR part 201, including §§ 201.10, 201.100(b), and other sections in subpart A and subpart B.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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